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FOREWORD

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SYMPOSIUM ON HEALTH CARE TECHNOLOGY: REGULATION AND REIMBURSEMENT

FOREWORD

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Health care technology is directly related to all three of the nation's health care crises—cost, access, and quality. Spending on technology is a primary reason for the crisis of cost,[1] reflected in the fact that health care spending is rising much faster than the rate of inflation and is becoming increasingly unaffordable for businesses, individuals, and the government. The crisis of cost, along with our dysfunctional system of private health insurance, also is accountable for the crisis of access—represented by the almost fifty million Americans who lack health insurance at some point during each year. Health care technology also is connected to the crisis of quality. Despite our lavish spending on new drugs, medical devices, and surgical procedures, Americans do not enjoy comparably better health states than citizens of other countries, and much of the harm that patients suffer at the hands of the health care system can be attributed to the loopholes and weaknesses in our regulatory mechanisms and to the use of high-tech interventions by overworked, underskilled, and inadequately trained health care professionals.

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1. *See* Thomas Bodenheimer, *High and Rising Health Care Costs Part 1: Seeking an Explanation*, 142 ANNALS INTERNAL MED. 847 (2005).

The health care system in turn is a casualty of the long-running struggle between the competing values of social welfare and individual self-aggrandizement. As played out in the health care arena, the contest has pitted not-for-profit against for-profit delivery models, health care professionalism against marketing and salesmanship, the plight of the sick and the poor against the indifference of the well and the well-off.

The Articles in this Symposium illuminate four different battlegrounds in this struggle. Michael Ash and Stephen Arons's piece focuses on the distortions in end-of-life care created by our jury-rigged health care entitlement system.[2] On the cost side, they acknowledge that few savings are to be had by replacing hospital care with hospice care. The economic incentives nevertheless result in some patients being deprived of proper care.

Hospice care supposedly is the most humane form of end-of-life care. Therefore, it might be presumed that dying patients would benefit from the fact that hospitals gain financially if they place patients in hospice care, either hospital-based or freestanding, and that Medicare Advantage managed care plans can profit from a quirk in the Medicare program that gets hospice patients off its books because their care is paid for by traditional Medicare. Ash and Arons point out, however, that Medicare pays hospices on a per diem basis, which discourages them from providing more expensive types of comfort care, such as chemotherapy and palliative surgery. The prerequisite of a prognosis of six months of remaining life before patients are eligible for hospice care under Medicare also creates discontinuities in care as patients are shifted from site to site as their condition worsens, or in some cases, improbably improves. Ash and Arons are particularly troubled by the lack of reimbursement for communicating end-of-life care options to patients and their families.

Many people nearing the end of their lives are covered by Medicaid rather than, or in addition to, Medicare. Ash and Arons note that federal law does not obligate Medicaid to cover hospice care, but that, currently, forty-seven states do so voluntarily. This raises the question whether they can continue to do so during the current economic meltdown, and what the consequences for patients would be if the hospice benefit disappeared.

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2. Michael Ash & Stephen Arons, *Economic Parameters of End-of-Life Care: Some Policy Implications in an Era of Health Care Reform*, 31 W. NEW ENG. L. REV. 305 (2009).

Timothy Hall's paper on direct-to-consumer (DTC) drug advertising confronts an aspect of one of the great con-jobs in health care cost containment.[3] When policymakers began worrying about the rising costs of health care, they quickly realized that a major problem was the absence of a market force for holding down spending. Historically, the system had relied on physicians, believed to be acting solely in the best interests of their patients, to order only those services that patients actually needed. But the growth of public and private health insurance changed that. Subjected to fee schedules by public and private insurers, physicians—who were reimbursed on a fee-for-service basis—simply took advantage of Roemer's Law (the fact that health care stands classic economic theory on its head by increasing demand to meet an increase in supply)[4] and increased their utilization of services, while insured patients had little financial exposure and thus little cause to complain.

The initial response to try to contain costs was for insurers to begin actively to question physician utilization, that is, to manage care. In this, insurers found justification in the work of John Wennberg and his colleagues; their small-area variation studies showed that there is no sound medical rationale for the widely divergent rates at which patients receive high-tech procedures.[5] If physicians are not making scientific treatment decisions, there is no reason why third-party payers cannot second guess them on the basis of cost. But physicians, outraged at having their clinical judgment questioned by mere MBAs, and patients, afraid that they were being denied medically necessary care, rebelled. Managed care reacted by backing off utilization review. Instead, using techniques such as capitation, whereby they paid physicians a fixed amount for each patient for whom they were responsible, insurers placed more financial risk on the physicians themselves. For a variety of reasons, not the least of which was the relentless development of new, cost-increasing medical technology, this too failed to bring spending under control. If physicians and insurers could not reign in utilization, who was left? The answer provided by conservative Republicans and centrist Democrats was: the patient. Except that, in

3. Timothy S. Hall, *Regulating Direct-to-Consumer Advertising with Tort Law: Is the Law Finally Catching Up with the Market?*, 31 W. NEW ENG. L. REV. 333 (2009).

4. Emily K. Abel, Elizabeth Fee & Theodore M. Brown, *Milton I. Roemer Advocate of Social Medicine, International Health, and National Health Insurance*, 98 AM. J. PUB. HEALTH 1596, 1596-97 (2008).

5. *See generally* John Wennberg & Aaron Gittlesohn, *Variations in Medical Care Among Small Areas*, SCI. AM. Apr. 1, 1982, at 120.

keeping with the tenets of neoclassic economics, they were no longer to be called "patients" but "consumers." Hence the solution to the crisis of cost became known as "consumer-driven health care."

One element of consumer-driven health care is direct-to-consumer advertising of prescription drugs. Previously, drug marketing targeted prescribing physicians. With few exceptions, such as for birth-control pills, drug manufacturers did not communicate information to patients about the risks, benefits, and recommended usage of their products. Direct-to-consumer advertising was not prohibited by law: manufacturers could advertise directly to patients so long as they described the target disorder but did not mention the name of the drug; or they could give the name of the company, but they could not link a drug to a disorder in consumer ads unless they included all of the information that the FDA required them to give doctors. This last approach effectively barred television ads, which were not long enough to display that much wording, and companies refrained from detailed print ads because they believed that patients would be frightened off if they read all the things that could go wrong from taking the drugs. Furthermore, tort law gave manufacturers a powerful incentive to avoid communicating directly with patients: the learned intermediary doctrine. So long as patients had to receive drug information from their physicians, they could not sue manufacturers for failing to give them adequate warnings about adverse effects.

This changed in 1997, when the FDA issued new guidelines that relaxed the disclosure requirements in ads to consumers.[6] Ads could tell patients to use a drug for a specific ailment so long as they provided certain limited information about side effects and a toll-free number that consumers could call for more information.

Direct-to-consumer drug ads fit right in with a consumer-driven health care approach: give patients adequate information and they can make wise, frugal decisions about which drugs to take. Moreover, it was well known that, whatever efforts they made to obtain the patient's informed consent to a procedure or treatment approach, physicians rarely sought informed consent for drug prescribing. Direct-to-consumer ads, in theory, could fill this information gap.

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6. Meredith B. Rosenthal et al., *Promotion of Prescription Drugs to Consumers*, 346 NEW ENG. J. MED. 498, 498 (2002).

But the reality of direct-to-consumer advertising reveals consumer-driven health care for the scam that it is. The ads do not give patients the information they need to make intelligent choices about which prescription drugs to take. Alternative medications are not listed, much less their pros and cons compared with the advertised product. The ads also do not mention the cost of the drug, or describe its cost effectiveness—that is, whether it will provide the patient with the biggest pharmaceutical bang for the buck. Instead, the incessant ads pound the name of the product relentlessly into patients' heads, along with the false message that it is a wonder drug that is far superior to anything else on the market. Equipped with this "knowledge," patients troop to their doctors' offices and demand prescriptions. Little do they know if studies of the drug show merely that it is marginally more efficacious than a placebo. It never occurs to them that the drug has not been compared with cheaper alternatives, or that, if it has, any extra benefit may be of no clinical significance. As embodied in direct-to-consumer advertising, consumer-driven health care is nothing more than a license for drug manufacturers and pharmacies to prey upon the public.

There is no reason to believe that consumer-driven health care would produce a different result when the medical care in question is a diagnostic test or surgical procedure rather than a drug. The only decision-making advantage patients have over physicians and managed care administrators is that patients have their own interests at heart. This is nothing to sneer at, but it is insufficient. There simply is no way the vast majority of patients can obtain the information and expertise to enable them to make informed health care decisions. In most respects, the information—the relationship between price and quality or outcome—simply does not exist. Indeed, doctors themselves do not have this information. This was recently underscored by a cover article in *BusinessWeek*, which quoted physician and health care-quality expert David Eddy as admitting: "The problem is that we don't know what we're doing."[7] Even when the information is obtainable, it is likely to be too complicated for most people to understand and process. How easy is it to select a health insurance plan from the handful of choices offered by your employer? What is it like for your parents to try to sort through several dozen different premium rates, deductibles, and

7. John Carey, *Medical Guesswork*, BUSINESSWEEK, May 29, 2006, *available at* http://www.businessweek.com/magazine/content/06_22/b3986001.htm.

drug formularies to pick a Medicare Part D drug plan?[8] How are worried, sick patients supposed to figure out how much of their health savings account to expend on an episode of illness?

Hall addresses one of the most pernicious implications of consumer-driven health care. A cardinal principle of the law is that a party should be responsible for the consequences of its bad decisions, rather than be able to shift the responsibility to someone else. In medical care, this traditionally has meant that, since physicians bear the ultimate responsibility for medical decision making, the physicians are liable for harm caused to their patients by their malpractice. Even when patients play a key role in the decision-making process or in causing harm to themselves, physicians are not generally relieved from liability; hence, courts refuse to deny compensation to patients who could be said to have been contributorily negligent[9] or to have assumed the risk.[10] For the most part,[11] this principle of liability survived the creation of the physician's duty to obtain the patient's informed consent, which was designed to empower patients by involving them in the decision-making process. But some commentators who embrace a law-and-economics approach argue that the informed consent doctrine warrants a revision in the classic allocation of fault between doctors and patients.[12] They are aided, perhaps unwittingly, by some patient-rights advocates, who urge patients to protect themselves by checking out the physician's training and credentials, and negotiating up front the terms of their patient-physician relationship.[13] If patients play a key role in making treatment decisions and in designing the terms

8. Susan Levine, *Seniors Find Medicare Drug Plan Options Bewildering; 'How Do You Pick?' Array of Deductibles, Premiums And Exceptions Perplexes Recipients and Advisers*, WASH. POST, Nov. 19, 2005, at A1.

9. *See, e.g.*, Martineau v. Nelson, 247 N.W.2d 409, 416 n.15 (Minn. 1976) (denying contributory negligence defense); Cowan v. Doering, 545 A.2d 159, 167 (N.J. 1988) (same).

10. *See, e.g.*, Tunkl v. Regents of Univ. of Cal., 383 P.2d 441 (Cal. 1963) (rejecting waiver-of-liability defense).

11. *See, e.g.*, Schneider v. Revici, 817 F.2d 987 (2d Cir. 1987) (holding that the jury could find that the patient had assumed the risk of unconventional therapy).

12. *See, e.g.*, Clark C. Havighurst, *Private Reform of Tort-Law Dogma: Market Opportunities and Legal Obstacles*, LAW & CONTEMP. PROBS., Spring 1986, at 143; *see also* James F. Blumstein & Frank A. Sloan, *Redefining Government's Role in Health Care: Is a Dose of Competition What the Doctor Should Order?*, 34 VAND. L. REV. 849 (1981); Glenn O. Robinson, *Rethinking the Allocation of Medical Malpractice Risks Between Patients and Providers*, LAW & CONTEMP. PROBS., Spring 1986, at 173.

13. *See, e.g*, Mary Greenwood, How to Negotiate With Your Doctor Like a Pro, http://ezinearticles.com/?How-to-Negotiate-With-Your-Doctor-Like-a-Pro&id=1739822 (last visited Apr. 15, 2009).

on which they will receive medical care, then it might seem to follow that they, rather than, or at least along with, the physician, should bear the costs of injurious mistakes.

In the context of direct-to-consumer drug advertising, this suggests that the patient, rather than the prescribing physician or the drug manufacturer, should bear the costs of injuries suffered from known adverse effects about which the patient is not properly informed. The theory of consumer-driven health care mandates that the patient-as-consumer ought to read up on drug labeling, doing further research if necessary in order to validate the information and understand the medical jargon. If, despite the warnings in the literature, patients nevertheless decide to use the drug and are harmed, they only have themselves to blame.

Hall roundly attacks this idea. His reasoning, unlike mine, is dispassionate. According to Hall, as a matter of economics, insulating the drug companies from liability when they advertise directly to consumers leads to inefficiency: "The law permits drug companies to communicate directly with patients, thus generating demand for the advertised drugs, but it insulates them from liability to those same patients based upon those communications." He concludes that "the law currently sets up a significant market distortion that overincentivizes expenditure on direct-to-consumer advertisements."[14] Hall points with approval to several court decisions that question the vitality of learned intermediary protection for these advertisers.

Extrapolating from Hall's argument, when patients are encouraged to make decisions on their own rather than defer to physicians and manufacturers, the law should afford them more, not less, protection. This would be a profound change in the consumer-driven health care approach that would reduce the likelihood that experts and entrepreneurs could take advantage of gullible, unsophisticated, or enfeebled patients. By giving patients an incentive to trust the advice of their caregivers, it also would tend to enhance the physicians' professionalism, rather than recast them as little more than tradesmen in an arm's-length relationship.

Karen Jordan's Article also focuses on the need to protect patients from harmful drugs. She discusses the doctrine of federal preemption, which has been used to thwart product liability suits brought against drug manufacturers under state law. As she argues in this exceptionally thorough piece, the courts should take a "hard

14. Hall, *supra* note 3, at 343.

look" at the FDA's claim that Congress gave it, rather than the states, the sole authority to determine the proper labeling for prescription drugs.

On one level, Jordan's Article is an essay on the intricacies of federalism and judicial review.[15] At a more fundamental level, it concerns efforts by the drug industry to sacrifice safety for profits by lobbying for "tort reform." The FDA did not assert its preemption argument against state product liability actions until the Bush administration took office. As Jordan explains in an earlier article:

> During the fourteen months immediately following Daniel E. Troy's appointment as FDA's Chief Counsel, he held at least fifty meetings with representatives of FDA-regulated industries. In December 2003, Troy acknowledged that the FDA was "deeply immersed in tort reform issues" and key Bush personnel noted that the "FDA's litigation strategy embodies 'good health policy and good tort reform.'"[16]

The FDA's action was part of a larger war against the tort system driven by an alliance of Chamber of Commerce lobbyists, organized medicine, and right-wing and centrist policy wonks.[17] Drug companies moan that tort liability will stifle innovation by stripping resources from research and development. As law professor Timothy Jost observes, however, this claim is, at best, oversold.[18]

The fourth article in this symposium is Richard Saver's, in which he discusses whether subjects in clinical trials should have a legal right to obtain continued access to the experimental modality after the study has ended.[19] The answer would seem to depend, in the first place, on why access is denied. On the one hand, the trial may show that experimental intervention provides statistically and clinically significant net benefit to patients, and by denying access, the sponsor simply is choosing to sacrifice the health of the subjects

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15. Karen A. Jordan, *Opening the Door to "Hard-Look" Review of Agency Preemption*, 31 W. NEW ENG. L. REV. 353 (2009).

16. Karen Jordan, *Agency Preemption and the* Shimer *Analysis: Unmasking Strategic Characterization by Agencies and Giving Effect to the Presumption Against Preemption*, 2008 WIS. L. REV. 69, 72 n.9.

17. *See* MAXWELL J. MEHLMAN & DALE NANCE, MEDICAL INJUSTICE: THE CASE AGAINST HEALTH COURTS—EXECUTIVE SUMMARY (2007), http://www.justice.org/pressroom/PressReleases/ExecutiveSummary.pdf.

18. Timothy Stoltzfus Jost, Pharmaceutical Research and Manufacturers of America v. Walsh: *The Supreme Court Allows the States To Proceed with Expanding Access to Drugs*, 4 YALE J. HEALTH POL'Y L. & ETHICS 69, 75 (2004).

19. Richard S. Saver, *At the End of the Clinical Trial: Does Access to Investigational Technology End As Well?*, 31 W. NEW ENG. L. REV. 411 (2009).

for the sponsor's economic self-interest, such as by not giving away an expensive drug for free. In that case, Saver's recommendations seem appropriate; namely, that institutional review boards (IRBs) require investigators to be clearer about the sponsor's policy on continued access when they seek informed consent, and that there be a presumption in favor of continued access. On the other hand, the sponsor may decide to abandon the product as not commercially viable; in that case, giving subjects a right to continued access could force the sponsor to continue to manufacture some of it, which may be extremely costly or even virtually impossible if supplies of raw materials stop being available. Saver anticipates this by recommending that IRBs be permitted to waive continued access for good cause. But often it may not be possible for an IRB to foresee the future circumstances that the sponsor may encounter.

In still other situations, the sponsor may conclude that the experiment did not demonstrate any efficacy for the experimental intervention, or not enough net benefit to justify FDA approval. The question then is whether the subjects should be able to form their own conclusions about the benefit provided by the intervention—such as that some subjects seemed to show improvement—and therefore require the sponsor to continue to supply them with it. This brings us back to consumer-driven health care, which might favor such an approach. But the courts have concluded that even terminally ill patients do not have a constitutional right to obtain access to unapproved drugs,[20] and the courts are unlikely to reach a different conclusion simply because the patients participated in a clinical trial.

Another issue is whether Saver would impose his presumption of continued access if the sponsor had abandoned the product at early stages of clinical testing, after Phases I or II, or only after the product had completed the large-scale Phase III trials required to convince the FDA that it was safe and efficacious. Saver's recommendation seems least appropriate if only Phase I studies have been conducted, since typically they are not designed to determine if the product works in patients. Even Phase II trials, which are not large enough to establish statistical significance (proof that the re-

20. *See* Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695, 697 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008) (holding that cancer patients have no right to drugs that have undergone Phase I clinical trials).

sult is not due to chance), nor adequate to detect adverse effects, may not be sufficient.

In considering objections to continued access, Saver points to the fact that subjects interact with investigators, not sponsors. This makes it difficult for courts to impose a legal obligation on the sponsor. Furthermore, he acknowledges that, since investigators may feel responsible to sponsors and to the study itself as well as to the subjects, some commentators question whether investigators even owe a duty of loyalty to their subjects, such that courts would be justified in requiring the investigators to address the issue of continued access during the enrollment process. It is true that the conflicting loyalties arising in the experimental context make the application of fiduciary doctrine more complicated between investigators and subjects than between physicians and patients. But clearly investigators cannot willfully sacrifice the health of a patient for the investigators' own interests; for example, they cannot lawfully abandon subjects injured by the experiment after it is over. Moreover, the investigators often *are* the subjects' physicians, in which case their fiduciary duty to the patient must be paramount. Even where this is not the case, the presence of conflicting interests is the justification for imposing fiduciary duties, not rejecting them; the law simply must decide to whom the investigators owe their primary loyalty.

Like the other Articles in this Symposium, Saver's operates on different levels. At one level, it is about the rights of subjects vis-à-vis sponsors and investigators. But on another level, his topic raises the question of what the proper motivation should be for people to agree to serve as subjects. Should people participate more out of altruism or self-interest? Saver's approach reinforces the latter: subjects ordinarily should be entitled to expect to continue to benefit after the trial is over. But an argument can be made that the main motivation ought to be a willingness to help others or to generate useful scientific knowledge. Indeed some studies, including most Phase I trials, are not intended to provide any benefit to the subjects, and even in later-phase investigations, subjects in control groups may never receive the experimental interventions. The tendency of subjects to misunderstand this and assume that they stand to gain something personal, in fact, is bemoaned as a "therapeutic misconception," which investigators and IRBs must guard against, not play upon. This same controversy is taking place in the realm of organ donation for transplantation, where some commentators

urge that the law be changed to allow donors to be financially rewarded.

CONCLUSION

All four of the Articles in this Symposium deal in some way with the issue of how the health care industry should be regulated. Ash and Arons debate how government-funded hospice services should be provided. For Hall, the question is whether drug companies that advertise directly to consumers should escape liability for product injuries. Jordan suggests that drug companies should be vulnerable to state products liability suits, and Saver argues they should be under some obligation to continue to provide experimental products to subjects.

But the elephant in the room is consumer-driven health care, which opens the door to the possibility that health care can be deregulated because patients can look out for themselves. Let us hope that the current ordeal of our economy, in which the supposedly most sophisticated among us were taken to the cleaners, has laid to rest the notion that health care technology can be distributed more fairly and efficiently the less it is regulated.